K041708

NOV 3 0 2004

IV. 510(k) Summary

Submitter

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Date Prepared

June 18, 2004

Trade Name

Enpath Safety Introducer

Common Name

Catheter Introducer

Predicate Device

TFX Medical Safety Needle with Introducer, K000665

Device Description

The Enpath Safety Introducer is designed to minimize needle stick injuries when used to introduce catheters, pacemaker leads and similar devices into the venous system. Sheath needles consisting of a peelable sheath over a needle, or peelable micro-introducers using the Seldinger Technique, are common methods for placing such devices. This Safety Introducer device combines various attributes of both the needle and the micro-introducer with the inclusion of a safety feature. The Safety Introducer allows for a one-step process of accessing the body. The Safety Introducer includes a safety shield which is spring-loaded in position during the ready-to-use state. After gaining vessel access, the needle subassembly is undocked from the introducer sheath and removed, leaving the sheath in the vessel for catheter placement. Removing the introducer sheath during standard practice passively advances (activates) the safety shield that locks in place. The safety shield covers the sharp of the needle bevel to protect patients and healthcare workers from accidental needle sticks.

The sheath body is constructed of PTFE and is filled with bismuth trioxide as a radiopacifier. The sheath handles, made of polypropylene resin, are overmolded onto the PTFE sheath tubing. The dilator is made of HDPE (high density polyethylene) and has a hub made of HDPE resin overmolded onto the dilator shaft. The front hub and the luer components are both molded of Polycarbonate resin. The needle and spring are stainless steel. The swivel luer cap and needle cover are both made of Polypropylene. UV cured adhesive is used during the assembly to hold the needle to the luer. The final assembly is coated with silicone lubricant from the tip of the needle to the handles of the sheath to reduce insertion force.

Sizes of the assembly range from 3.5 FR to 7FR. The needle is 21gauge for all French sizes, and the materials and construction are the same for all French sizes. The Safety Introducer will be packaged and EtO sterilized for one time use in a Tyvek pouch. The packaging configuration may include sterile kit containing a stainless steel guidewire or a bulk, non-sterile configuration.

Intended Use

The Enpath Safety Introducer is intended to minimize needle stick injuries when used to introduce catheters, pacemaker leads and similar devices into the venous system

Technological Characteristics

The device is technologically equivalent to other safety needle and introducer products.

Summary of Studies

A Risk Analysis for the Safety Introducer was performed per Enpath Medical, Inc internal procedure, WI42020, *Hazard Analysis, FMEA and Risk Analysis*. This document is modeled closely after European Standard ISO 14971: 2000 Medical Devices - *Application of Management to Medical Devices*

The performance testing for this device included testing to verify that the device safety function performed effectively. Additional testing verified that the device performed per specification requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2004

Ms. Karyl D. Haskell
Quality Assurance and Regulatory Affairs Manager
Enpath Medical Incorporated – Delivery Systems Division
15301 Highway 55 West
Minneapolis, MN 55477

Re: K041708
Enpath Safety Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: 74 DYB
Dated: October 20, 2004
Received: October 21, 2004

Dear Ms. Haskell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Indications for Use

Indications for Use

510(k) Number (if known): ~~Not Assigned~~ K041708

Device Name: Enpath Safety Introducer

Indications For Use: The Enpath Safety Introducer is intended to minimize needle stick injuries when used to introduce catheters, pacemaker leads and similar devices into the venous system

Prescription Use ✓ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kuchner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041708